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(54) Filter device

(57) A filter device for medical fluids comprises a plastics housing 24 having an inlet 28 and an outlet 30, a microporous filter membrane 26 in the housing between the inlet and outlet and a support screen 32 for the filter membrane downstream of the filter membrane, the screen and filter membrane being heat-sealed to the housing around their peripheries. The membrane and screen are sealed along a groove (36) formed in the housing around a flow passage between the inlet and the outlet. The housing includes a second membrane (58) serving as an air vent.

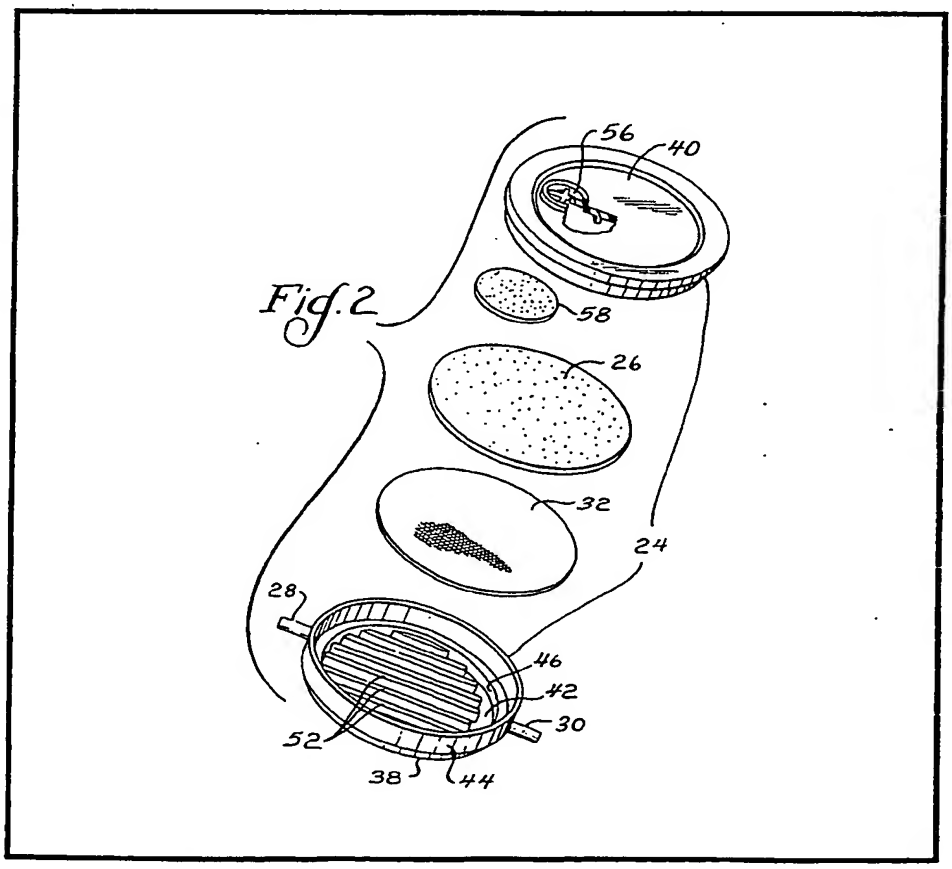

Fig.2

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Fig. 1

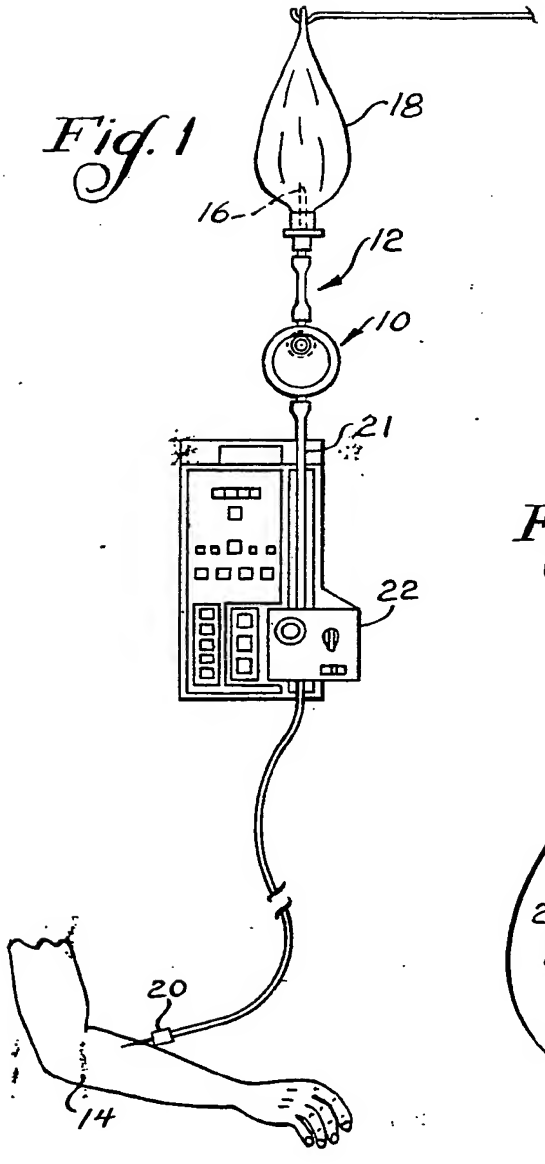
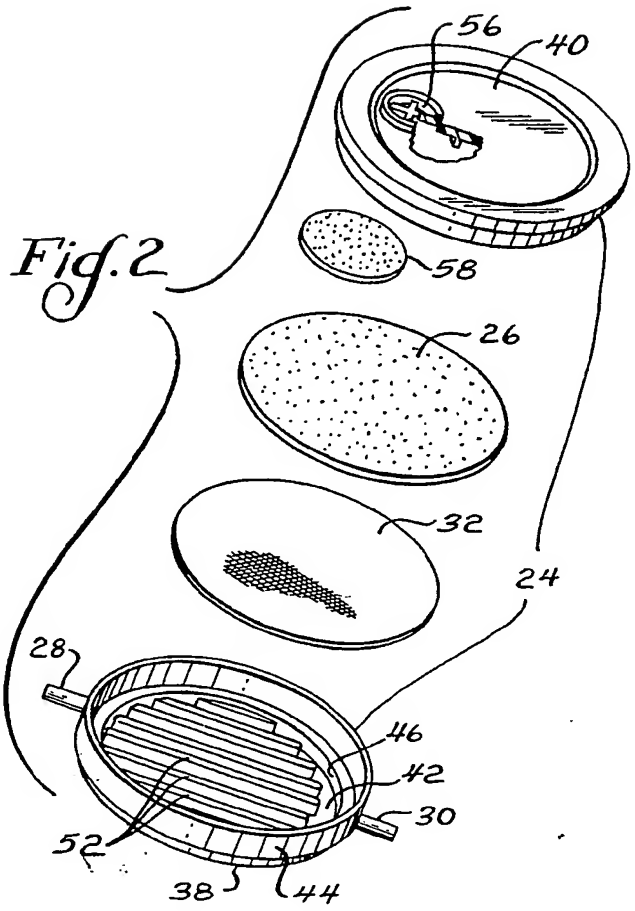


Fig. 2



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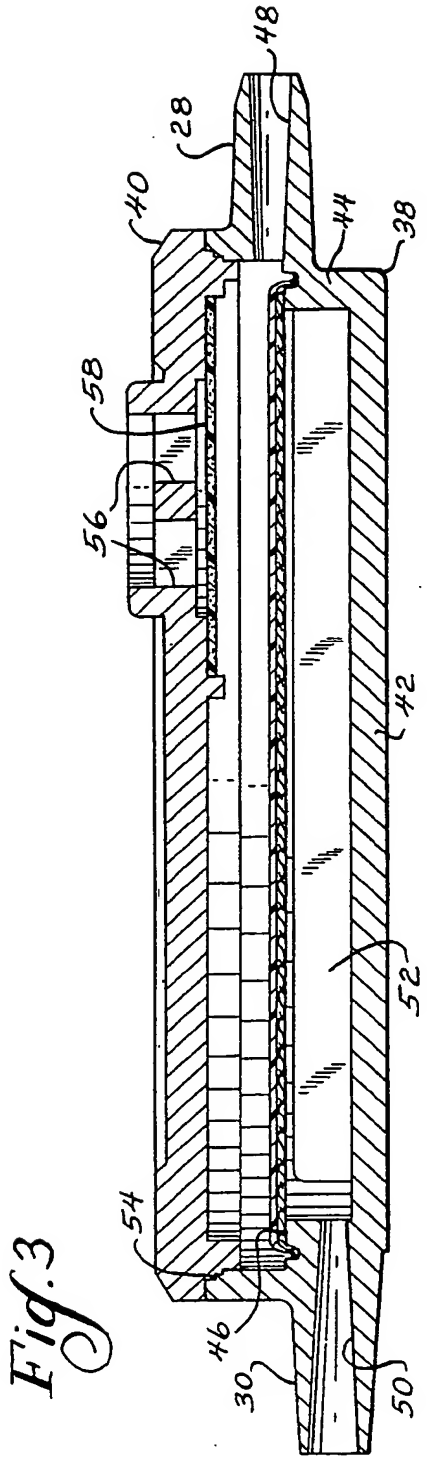

Fig. 3

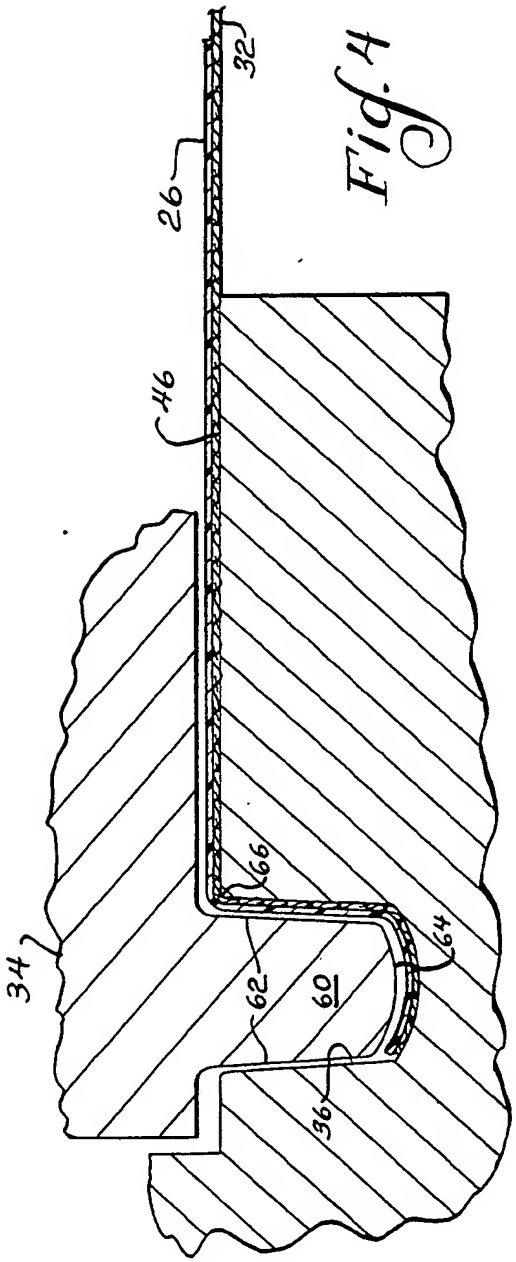

Fig. 4

SPECIFICATION

Filter device

The present invention relates to a filter device of the type which employs a microporous membrane to filter medical fluids.

Microporous filters are being increasingly used in the filtration of medical fluids, and particularly in the intravenous administration of parenteral solutions. The filters are usually provided in-line in a liquid administration set, which is connected at one end to an elevated reservoir of solution and, at the other end, to a needle inserted into the patient's vascular system, to filter the parenteral solution as it is administered to the patient. The filters usually have sufficiently small pores to remove particulate matter and may even be small enough to filter out bacteria. The filter normally used for parenteral solutions and the like is a microporous membrane which is very thin and fragile and is subject to damage by mishandling to excessive pressure. Even in a gravity flow liquid administration set, most filters have used a grid or support structure below the membrane to prevent rupturing by the fluid head in the administration set. One type of filter which has been successfully employed by Travenol Laboratories, Inc. is shown in U.K. Patent Application No. 7846539.

Although such a filter is quite satisfactory in a gravity flow system, it is often desirable to employ a precisely controlled pump in conjunction with the administration systems to provide a carefully controlled about of parenteral solution to the patient. Thes pumps are capable of generating substantially greater pressures than are encountered in a gravity flow system, and filters that may work well in a gravity flow administration set may not be suitable for use in a pump-controlled system.

For example, one such pump is described in U.K. Patent Applications Nos. 3057/77 Serial No. 1556293 and 49066/77. Serial No. 1556294. This pump is a peristaltic-type pump in which moving rollers engage a portion of the flexible tubing of the administration set to precisely feed a controlled amount of liquid to the patient. If a filter were mounted above the pump, i.e., upstream of the pump, it may be possible for the pump to draw a very high vacuum on the filter. A typical filter for gravity flow administration set may not be capable of resisting the pressure or vacuum applied to it.

The present invention provides from one aspect a filter device for medical fluids comprising a plastics, heat-deformable housing, inlet and outlet openings in said housing, a flow path within said housing communicating between said inlet and outlet openings, a microporous filter membrane carried within said housing and spanning said flow path to filter the fluid passing therealong, a plastics support screen spanning said flow path, downstream of said filter membrane and closely adjacent thereto to support said membrane against rupture under the pressure of filtering liquid, said support screen being integrally sealed to said housing at least around the periphery thereof.

The invention also resides a method for providing a reinforced filter within a heat-deformable plastics housing comprising inlet and outlet openings, a passageway for the flow of liquid therebetween, and an annular sealing surface around the passageway, said method comprising placing a plastics, heat-sealable support screen in said passageway with the peripheral edge of the screen extending over the annular surface,

pressing a heated annular die against the peripheral edge of the screen until a continuous groove is formed in said annular surface and said screen is integrally sealed within said groove,

placing a plastics, heat-sealable microporous filter membrane over the support screen with the peripheral edge of the membrane extending over the annular sealing surface, and

pressing a heated annular die against the peripheral edge of said filter membrane until it is integrally sealed within said groove.

In this specification, the term "support screen" includes a support membrane.

Reference is now made to the accompanying drawings, wherein:–

Figure 1 depicts a filter device according to the invention employed in a parenteral administration set which is used in conjunction with a precision infusion pump.

Figure 2 is an exploded perspective view of the filter device.

Figure 3 is a vertical cross-sectional view taken along line 3–3 of Fig. 1.

Figure 4 is a substantially enlarged sectional view of the portion circled in Fig. 3, illustrating the means for sealing the reinforced filter membrane.

The present invention is generally embodied in a filter device 10 secured in-line in a liquid administration set 12 for administering liquid in a precisely controlled manner to a patient 14. One end of the set had a spike 16 insertable into reservoir of fluid, such as a collapsible plastics bag 18 of the type sold under the trademark Viaflex by Travenol Laboratories, Inc., of Deerfield, Illinois. The other end of the tubing has a hub 20 which may be secured to a needle that had been inserted into the vascular system of the patient. A portion of the plastics tubing 21 between the ends of the set is positioned within a pertistaltic-type pump 22 which precisely controls the flow of liquid from the reservoir into the patient.

The filter device 10 is uniquely designed to withstand the forces applied to it by the action

of the pump 22. The filter device has a two-part plastics housing 24 with a microporous filter membrane 26 sealed between an inlet opening 28 and outlet 30 in the housing. The membrane is reinforced against undue flexing or breakage by a flexible support screen 32 secured closely adjacent the underside of the filter membrane.

Both the support screen 32 and the filter membrane 26 are preferably made of plastics material and sealed to the housing 24. As shown in Fig. 4, in either a one or two-step operation, a heated annular die 34 is pressed against a peripheral edge portion of the filter membrane and support screen, forming an annular recess or groove 36 in the housing and heat sealing a portion of the peripheral edges of both along at least one of the wall surfaces within the groove. This not only secures and seals the filter membrane and reinforcing support screen in place, but the pressing of the edge of the screen into the groove serves to draw or tighten the screen to provide a flat, smooth support surface immediately beneath the filter membrane, which is likewise pressed or drawn into the groove.

Turning now to a more detailed description of the preferred embodiment of the present invention, the two-part filter housing 24 is preferably made of clear, rigid but heat-deformable plastics material such as the acrylic plastics material available under the trademark Plexiglas, type DR, from the Rohm and Haas Co. of Philadelphia, Pennsylvania. The housing includes a shallow disc-shaped base 38 covered by a substantially flat cap 40. The base includes a circular bottom wall 42 and an upstanding sidewall 44 which has an internal annular flat ledge or shoulder 46 upon which the filter membrane and support screen rest.

Inlet and outlet openings 28 and 30, respectively, are provided in the housing by elongated tapered ports integrally formed in the sidewall 44. Tapered bores 48 and 50, respectively, extend through the inlet and outlet ports and communicate through the sidewall 44 with the interior of the housing. The inlet and outlet ports are positioned on opposite sides of the shoulder 46 so that fluid passing through the filter devise must pass through the filter membrane 26 which rests on the shoulder and spans the filter housing. The sidewall of each port is tapered slightly along its length and more drastically at the tip end for ease of insertion into the lumen of the plastics tubing 21 of the administration set 12.

The inlet port 28 is positioned in the sidewall 44 above the shoulder 46. To help in preventing excessive sagging or bending of the filter membrane 26 from the pressure of fluid flowing through it, a series of parallel support ribs 52 are provided below the membrane. The ribs 52 are preferably moulded integrally with the base member 38 and, as best seen in Fig. 3, extend from the bottom wall 42 to just below the shoulder 46 on which the membrane is carried. The ribs do not extend fully across the base member. Rather, referring back to Fig. 2, one end terminates short of the sidewall 44 so that liquid flowing through the membrane is channelled to the outlet port 30.

The open side of the base 38 is closed and sealed by the generally flat, circular cap 40. The inside edge of the base sidewall 44 is stepped at 54 for close fitting with a matching construction on the top cap. The top cap and base may be sealed together by sonic welding, solvent-bonding or the like.

Although the utility of the present invention has a wider application, the specific filter illustrated in the drawings is designed to assure that liquid only, and no gas or air passes through the administration set. Any gas separated from the solution is vented to the atmosphere. This is accomplished by employing a pair of filter membranes that are selectively permeable to gas or liquid. The filter membrane 26 through which the parenteral solution passes is preferably "hydrophilic". That is, when wetted by solution, it is permeable to liquid but not gas. This has the beneficial effect of removing gas bubbles or the like which may be entrained in the parenteral solution and which, preferably, should not pass to the patient.

To vent the gas separated by the hydrophilic filter membrane, the cap 40 has an off-centre vent 56. A "hydro-phobic" filter membrane 58, which is liquid-repellent and gas permeable, is sealed against the underside of the cap below the vent to permit gas to vent to permit gas to vent but to prevent fluid from escaping through the vent. A well-known, naturally hydrophobic material frequently used in such applications is polytetrafluoroethylene. One type of hydrophobic filter made of this material, which has been successfully employed is type L10931 from the Gore-Tex Company of Elkton, Maryland. The technique for attaching the filter material is described more fully in U.K. Patent Application No. 7846539.

The hydrophilic filter membrane 26 through which the solution or medical fluid passes, is a very thin and fragile membrane. The preferred material for filtering aqueous parenteral solutions is made of mixed esters of cellulose, although other materials compatible with the fluid passing therethrough may also be used. Similarly, the pore size of the filter membrane may vary, so long as it is sufficiently small to filter out the desired particulate. For filtering parenteral solutions and the like, it is desirable that the filter membrane have an extremely small pore size, preferably less than .5 microns to remove microscopic particulate as well as some bacteria. In the illustrated em-

bodiment, the membrane preferably has a mean average pore size of about .22 microns to remove most bacteria and particulate from the liquid being filtered. With the materials and pore sizes described, once the filter membrane becomes wetted by liquid passing through it, it becomes "hydrophilic". That is, liquid can pass through the filter, but gas or air entrained in the liquid is effectively blocked.

To prevent excessive binding and resultant breaking of the hydrophilic membrane 26 under the pressure of the liquid flowing through it, the membrane rests on the non-rigid, plastics support screen 32. Like the filter membrane, the support screen rests on the annular shoulder 46, spanning the base 38. The support screen may be made from any plastics material that is heat sealable to the plastics housing and is compatible biologically and chemically with the solution being filtered. The support screen itself should have a pore size sufficiently large, preferably greater than 50 microns, so as not to restrict the passage of liquid through the filter membrane. The support screen should also be sufficiently strong to reinforce the filter membrane; a tensile strength of at least 12,000 psi is believed to be satisfactory. In the preferred embodiment, the screen is a very thin, flexible but strong nylon membrane. One such nylon screen that has been used successfully is type HC-3-53 from Tetko Inc., of Elmsford, New York. This screen is about 50 microns thick and is very flexible. It has an average pore of about 53 microns, which does not impede the flow of liquid significantly, and a tensile strength of about 12,000 psi, which provides a satisfactory reinforcement for the filter membrane.

The filter membrane 36 and support screen may be secured to the filter housing in either a one or two-step operation. Both the membrane and screen are circular and are cut to an appropriate size so that a peripheral edge overlaps the shoulder or ledge 46 of the base 38. In the two-step operation, the support screen and filter membrane are sealed separately, the screen first. The nylon screen is placed on the shoulder 46 and a heated die 34 is lowered into contact with the support screen or membrane. The die preferably has an annular sealing rib or ring 60 which has slightly tapered sidewalls 62 and a curved end wall 64. The width of the end wall is about .040 inches. The heated sealing ring engages the peripheral edge of the support screen and presses it against the shoulder 46. The heat from the ring melts the plastic of the shoulder and forms the channel or groove 36 continuously around the shoulder 46. The shape of the groove mirrors the shape of the heated ring 60, it has an upwardly curving bottom wall surface and outwardly diverging sidewall surfaces.

When the heated die 34 and support screen 32 are properly aligned on the shoulder, the ring 60 forces the peripheral edge of the screen into the channel or groove as the heating and melting occurs. Typically, as shown in Fig. 4, the outside edge of the screen will line the bottom and inner sidewall of the groove. The die is sufficiently hot that it also melts a portion of the nylon screen as the groove is formed, which coalesces with a melted portion of the housing to integrally attach and seal the screen thereto. Close examination of the seal provided between the nylon screen and the housing shows that although it is sealed along the bottom and sidewall of the groove, it is sealed particularly well along the bottom wall. The heated action of the ring 60 also appears to help smooth the outer surface of the screen along the sidewall of the groove for later lamination and sealing of the hydrophilic filter membrane 26.

The action of the sealing ring 60 against the peripheral edge of the screen 32 has a further advantage. As the shoulder 46 melts to form the groove, the ring presses the edge of the screen into the groove, drawing and pulling the screen over the inside edge 66 of the groove. This tensions the screen to provide a taut, smooth supporting surface for the hydrophilic filter membrane 26.

For sealing the support screen to the shoulder, it is important that the sealing ring be heated to high enough temperature, applied with enough pressure and held against the screen for enough time to melt the housing and the nylon support screen sufficiently to form the groove 36 and to integrally heat seal the screen and housing together. One combination that has been found to work satisfactorily is a die heated to about 375°F. and pressed against the shoulder with 35 psi of air pressure applied across a 4 inch diameter air cylinder which drives the die against the shoulder. With this combination, a satisfactory seal is provided when the die is held in place for about 2 seconds. Depending on manufacturing limitations or requirements, other combinations of time, temperature and pressure could also be found which adequately seals the support screen to the filter housing.

After the support screen 32 is sealed to the housing, the die is withdrawn and the hydrophilic membrane 26 is positioned over the screen. The die 34 is then lowered a second time to engage a peripheral edge portion of the filter membrane, pressing the edge into the channel 36 formed from previous operation. The die is held in place with sufficient pressure and for a sufficient time to melt the filter membrane and a portion of the screen to at least seal them integrally together. Depending on the die temperature and the pressure and time it is pressed against the filter membrane a portion of the housing may also melt so that molten plastics molten plastics

material from the membrane, screen and housing coalesces in a continouous seal. For manufacturing efficiency, the time, temperature and pressure is preferably the same as for the first step of sealing the support screen. As with the screen, the edge of the membrane lines the bottom and inner sidewall of the channel 36. Although the filter membrane is believed to seal along both the bottom and side-walls, close examination had revealed that it is sealed particularly well along the inner sidewall against the smooth surface of the nylon screen which was formed from the previous operation.

As noted before, the screen 32 and filter membrane 26 are sealed along the entire peripheral edge so that they span the sidewall 44, and any liquid passing between the inlet and outlet must pass through the filter membrane and the support screen.

The nylon screen 32 and hydrophilic membrane 26 may also be sealed in a one-step operation, which from a manufacturing standpoint, is more efficient. With this procedure as in the one described above, both screen and filter membrane are sized so that their peripheral edges overlap the shoulder 46 of the base member 38. Both the screen and membrane are positioned on the shoulder, and, as before, the sealing ring portion 60 of the heated die 34 is pressed against the peripheral edge of the filter membrane and support screen, melting the channel 36 into the shoulder. The die us held in this operative position against the shoulder until the housing has melted sufficiently to form the channel or groove 36 and the screen and membrane are melted enough to seal together integrally and to the housing along the inside of the groove or channel.

Although a range of die temperatures, pressures and contact time may be used for the one-step sealing operation, in the preferred embodiment, the die 34 is heated to about 375°F. and pressed against the shoulder 46 by an air cylinder (not shown) having a piston diameter of about 4 inches. The air line pressure to the cylinder is about 70 psi, and the die is held against the shoulder for about 2.5 seconds at this pressure. As noted earlier, this pressure of the die sealing ring 60 causes the shoulder to melt and form the channel or groove 36 into which the peripheral edge of the screen and membrane are pressed, lining at least the inside and bottom wall surfaces of the groove. As in the two-step precess, this stretches the screen to provide a taut support surface for the membrane thereabove. Even with this construction, when a pressure differential is applied across the filter surface, the membrane and screen may flex slightly, but the support ribs 52 therebelow prevent further spending or stretching of the filter membrane, and the screen prevents the filter membrane from being drawn down between adjacent support ribs.

Thus, it may be seen that with the present invention, a non-rigid, biologically compatible support screen is provided below a filtering membrane with a sealing and attachment arrangement for both that is both easy and economical to provide. It has been found that with the present construction, the filter membrane does not bend sufficiently to fracture or break even when almost a complete vacuum is created in the space downstream of the filter membrane.

CLAIMS

1. A filter device for medical fluids comprising a plastics, heat-deformable housing, inlet and outlet openings in said housing, a flow path within said housing communicating between said inlet and outlet openings, a microporous filter membrane carried within said housing and spanning said flow path to filter the fluid passing therealong, a plastics support screen spanning said flow path, downstream of said filter membrane and closely adjacent thereto to support said membrane against rupture under the pressure of filtering liquid, said support screen being integrally sealed to said housing at least around the periphery thereof.

2. A filter device in accordance with claim 1 wherein said support screen is a nylon membrane.

3. A filter device in accordance with claim 1 or 2 wherein said housing includes an annular surface circumscribing the flow path, the periphery of said support screen being sealed along said surface, and said microporous filter membrane also being made of plastics material and being sealed along said annular surface overlying the support membrane.

4. A filter device in accordance with claim 3 wherein said support screen and filter membrane are integrally sealed, at least in part, along a groove formed in said annular surface of said housing.

5. A filter device in accordance with claim 4 wherein said support membrane is sealed at least along the bottom of said groove and said membrane is sealed at least along a side of said groove.

6. A filter device in accordance with any preceding claim, wherein said housing further comprises spaced support ribs underlying said support screen.

7. A filter device in accordance with any preceding claim, wherein said support screen has a pore size of at least 50 microns.

8. A filter device in accordance with any preceding claim, wherein said filter membrane is hydrophilic to prevent the passage of gas, said housing being vented upstream of said membrane to permit the removal of gas removed by the filter.

9. A filter device in accordance with any

preceding claim, wherein said filter membrane has a pore size of less than one micron.

10. A filter device for filtering medical fluids comprising a plastics, heat-deformable housing, inlet and outlet means in said housing, a flow path in said housing communicating between the inlet and outlet means, said housing defining an annular shoulder circumscribing said flow path, a plurality of spaced support ribs carried by said housing in said flow path adjacent said shoulder, a plastics support screen upstream of and overlying said support ribs and spanning said flow path with its peripheral edge sealed to said annular shoulder, a microporous filter membrane upstream of and overlying said support screen and spanning said flow path with its peripheral edge sealed to said annular shoulder, said annular shoulder comprising a continuous groove, said peripheral edges of said support screen and filter membrane being sealed integrally to said shoulder within said groove.

11. A filter device in accordance with claim 10 wherein said groove includes a bottom wall and a pair of side-walls, said support screen and filter membrane being sealed to at least one of said walls of said groove.

12. A filter device in accordance with claim 11 wherein said support screen is sealed to said bottom wall and said filter membrane is sealed to one of said sidewalls.

13. A medical fluid filter device comprising a heat-deformable plastics housing, inlet and outlet openings in the housing, a passageway between said inlet and outlet openings, an annular sealing surface around the passageway comprising a groove along the sealing surface, and a microporous filter membrane and a support screen therebeneath spanning the passageway and integrally sealed to the annular surface along at least a portion of said groove therein.

14. A method for providing a reinforced filter within a heat-deformable plastics housing comprising inlet and outlet openings, a passageway for the flow of liquid therebetween, and an annular sealing surface around the passageway, said method comprising placing a plastics, heat-sealable support screen in said passageway with the peripheral edge of the screen extending over the annular surface, pressing a heated annular die against the peripheral edge of the screen until a continuous groove is formed in said annular surface and said screen is integrally sealed within said groove, placing a plastics, heat-sealable microporous filter membrane over the support screen with the peripheral edge of the membrane extending over the annular sealing surface, and pressing a heated annular die against the peripheral edge of said filter membrane until it is integrally sealed within said groove.

15. A method in accordance with claim 14 wherein said support screen and filter membrane are simultaneously sealed to said annular surface.

16. A method in accordance with claim 14 or 15 wherein said die has an annular, projecting sealing ring that engages said peripheral edges of said support screen and filter membrane.

17. A method in accordance with claim 14, 15 or 16 wherein said support screen is drawn into said groove by said sealing ring to tighten said screen to provide a smooth support surface for said filter membrane.

18. A method in accordance with claim 14, 15, 16 or 17 wherein said groove includes a bottom wall and a pair of sidewalls, said support screen being sealed at least along the bottom wall, said filter membrane being sealed at least along one of the sidewalls.

19. A method for providing a reinforced filter within a heat-deformable plastics housing comprising inlet and outlet openings, a passageway for the flow of liquid therebetween, and an annular sealing surface around the passageway, said method comprising placing a plastics heat-sealable support screen in said passageway with the peripheral edge of the screen extending over the annular surface, placing a plastic, heat-sealable, microporous filter membrane over said support screen, with the peripheral edge of said membrane extending over said annular surface, pressing a heated die against the peripheral edges of said screen and membrane until said annular surface is melted to form a groove therein and said peripheral edges are integrally sealed within said groove.

20. A method in accordance with claim 19, wherein said die includes a projecting ring that engages the peripheral edges of said screen and membrane.

21. A method in accordance with claim 20, wherein said ring has a bottom wall and a pair of sidewalls to form a matching groove, said screen and membrane being pressed into said groove to line the bottom wall and at least one of said sidewalls, said screen being integrally sealed to at least the bottom wall of said groove, said membrane being sealed to at least the sidewall it lines.

22. A method in accordance with claim 20 or 21 wherein in the step of pressing the die against said peripheral edges draws said screen tightly across the fluid flow path to provide a smooth supporting surface for said membrane.

23. A filter for medical fluids constructed substantially as herein described with reference to the accompanying drawings.

24. A method of providing a reinformed filter in a heat-deformable plastics housing, said method being substantially as herein described with reference to the accompanying drawings.

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